



## KURARAY MEDICAL INC.

Dental Material Department  
12-39, 1-Chome, Umeda, Kita-ku, Osaka 530-8611, JAPAN  
Phone : +81-6-348-2603  
Facsimile: +81-6-348-2552

KO12740

SEP 14 2001

### 510(k) SUMMARY

1. Submitter

- |                             |  |
|-----------------------------|--|
| 1) Name                     | KURARAY MEDICAL INC.   |
| 2) Address                  | 1621 Sakazu, Kurashiki, Okayama 710-8622, Japan  |
| 3) Contact person           | Koji Nishida<br>DENTAL MATERIAL DEPARTMENT   |
| 4) Date                     | August 9, 2001   |
| 5) Contact person in U.S.A. | Masaya Sasaki<br>30th Fl. Metlife Building, 200 Park Avenue, New York,<br>NY 10166<br>Telephone : (212)-986-2230<br>1-(800)-879-1676<br>Facsimile : (212)-867-3543 |

2. Name of Device

- |                        |   |
|------------------------|---|
| 1) Proprietary Name    | CLEARFIL AP-X                               |
| 2) Classification Name | Tooth shade resin material (21CFR 872.3690) |
| 3) Common/Usual Name   | Composite resin restorative                 |

3. Predicate device:

Kuraray Co., Ltd. will transfer the medical device business and the relevant functions including manufacturing facilities to its subsidiary company named Kuraray Medical Inc. on October 1<sup>st</sup> 2001. The aim of 510(k) submission is to alter the name and address of manufacturer, and not to intend other changes.

The predicate device is as follow.

- |                                       |           |
|---------------------------------------|-----------|
| 1. CLEARFIL AP-X by Kuraray Co., Ltd. | (K943168) |
|---------------------------------------|-----------|

4. Description for the premarket notification

This product is classified into Tooth shade Resin Material, CFR 29 Section 872.3690, because it is a device composed of materials such as bisphenol A glycidylmethacrylate (Bis-GMA) intended to restore carious or structural defects in teeth.

5. Statement of the intended use

The intended uses of this device are as follows. They are completely the same as CLEARFIL AP-X manufactured by Kuraray Co., Ltd. (K943168).

- 1) Class I, II, V restorations of posterior teeth
- 2) Class III, IV, V restorations of anterior teeth
- 3) Cervical cavities or defects involving root surfaces

6. Statement of the technological characteristics and safety

This device is essentially the same as CLEARFIL AP-X manufactured by Kuraray Co., Ltd. (K943168). Therefore the technological characteristics, chemical ingredients and safety of this

device are completely the same as CLEARFIL AP-X.



SEP 14 2001

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Kuraray Medical Incorporated  
C/O Ms. Masaya Sasaki  
Kuraray America, Incorporated  
30<sup>th</sup> Floor Metlife Building  
200 Park Avenue  
New York, New York 10166

Re: K012740

Trade/Device Name: Clearfil AP-X  
Regulation Number: 872.3690  
Regulation Name: Composite Resin Restorative  
Regulatory Class: II  
Product Code: EBF  
Dated: August 9, 2001  
Received: August 14, 2001

Dear Ms. Sasaki:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

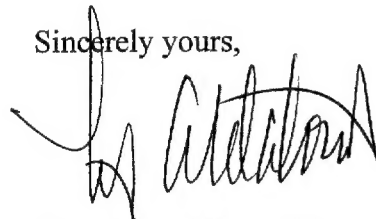
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (section 531-542 of the Act; 21); CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Timothy A. Ulatowski", is written over the typed name.

Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K012740

510(k) Number (if known): K012740

Device Name: CLEARFIL AP-X

### Indications for Use

CLEARFIL AP-X is indicated for the following applications:

- 1) Class I, II, V restorations of posterior teeth
- 2) Class III, IV, V restorations of anterior teeth
- 3) Cervical cavities or defects involving root surfaces

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)


\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K012740